

Applicants : JIN, et al.
U.S. Serial No.: 09/886,555
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Applicants claimed invention is an emulsion not a suspension. Both emulsions and suspensions are formed from two immiscible phases: a continuous phase and dispersed phases that are separated by the continuous phase. However, the dispersed phases of emulsions are liquid while that of suspension are solid. The liquid dispersed phases will fuse with each other to form a combined bulk phase if they have chance to contact, while the solid particles do not.

Emulsions, at least those in pharmaceutical systems, are regarded as those that possess sufficient stability to exist for a period of time without continuous shear stress. Some immiscible liquids may form "emulsions" only if a continuous shear stress (stirring for example) is applied. As soon as the shear is removed, the dispersed phases of these "emulsions" start to fuse and form a block phase in a short period. These shear-dependent instantaneous "emulsions" are normally not regarded as pharmaceutical emulsion systems. They are used as an intermediate state for the processes of emulsifying polymerization or emulsifying cross-linking.

There is no a general definition regarding the life-time of stable emulsions. Nevertheless, an "emulsion" that can only exist under a continuous shear stress is never regarded as an emulsion system, let alone a stable emulsion.

Claim Rejections - 35 USC § 102

The Examiner further rejected claims 1, 3 & 6-11 under 35 U.S.C. 102(b) as being anticipated by Hennink, et al (WO98/20093; hereinafter, Hennink). In response but without conceding the correctness of the Examiner's position to expedite the prosecution of this application, Applicants' new claim 13 has explicitly recite "without cross-link".

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Accordingly, Hennink cannot anticipate the claimed invention. A figure of schematic description of the differences between Aqueous two-phase system, Hennink's system and Jin's system is attached hereto as **Exhibit A** and a figure of Jin's droplet and Hennink's particle is attached hereto as **Exhibit B**.

In Hennink's method, another hazardous factor, cross-linking agents, are introduced. As macromolecules, proteins have abundant reactive moieties such as hydroxyls, amino groups, carboxylic groups, thiol groups and so forth. When the polymer chains within the dispersed phases to react with each other through cross-linking agents (or species), it is very likely that proteins are involved in the reaction.

Hennink's method Can not create a stable (or say self-standing) aqueous-aqueous emulsion. Because of that, they must cross-link (solidified) the polymer (modified dextran) within the dispersed phases under continuous stirring to prevent fusion between them.

Hennink's method can never solve the problems created by itself: the need of cross-linking agents. Cross-linking agents can be serious hazards to proteins which normally have abundant reactive functional groups.

A stable (self-standing) aqueous-aqueous system has never been reported up to date, let alone anticipated from Hennink's method.

CONCLUSION

Applicants believe that all grounds of objections and rejections raised in June 3, 2003 Office Action have been


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answered and an allowance of this application is earnestly requested.

If a telephone interview would be of assistance in advancing prosecution of the subject application, Applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee is deemed necessary in connection with the filing of this Amendment. However, if any additional fee is required, authorization is given to charge the amount of any such fee to Deposit Account No. 50-1891.

Respectfully submitted,



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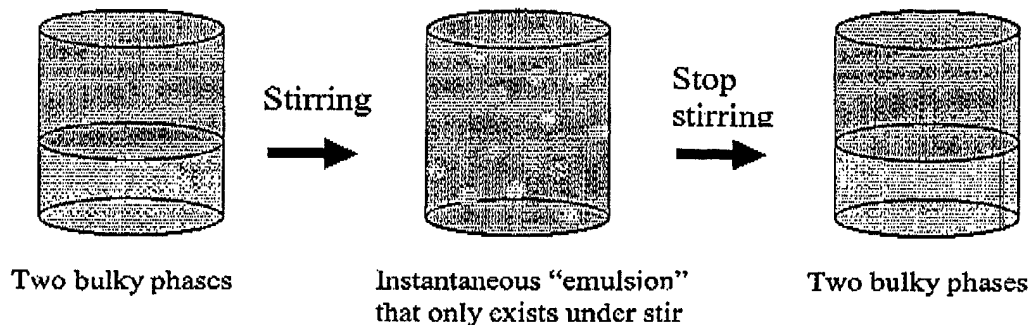
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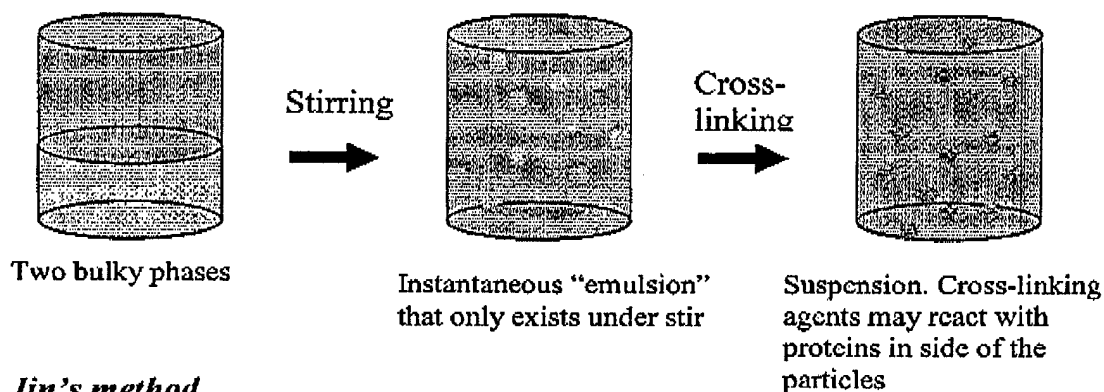
Exhibit A

Schematic Description of the Differences between Aqueous Two-phase System, Hennink's System and Jin's System

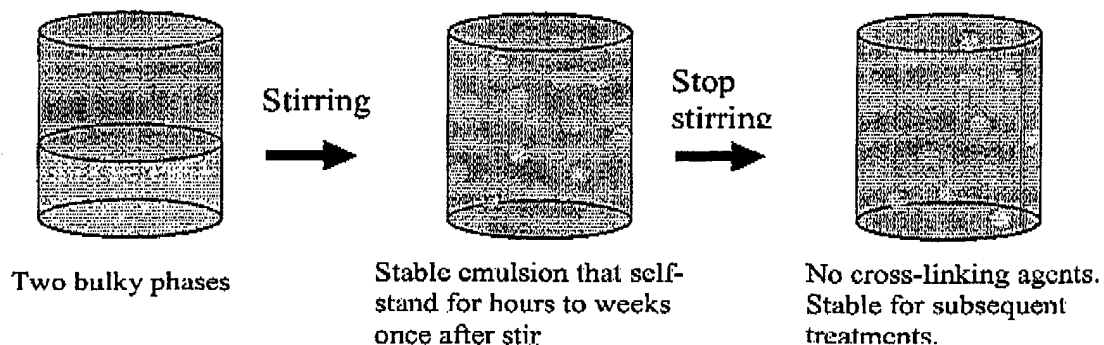
Aqueous two-phase system



Hennink's method



Jin's method



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Exhibit B

